DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2015

United Imaging Systems (Beijing) Co., Ltd.
% Mr. Jun Peng
Principal Consultant
P&L Scientific, Inc.
6840 SW 45th Lane, Unit 5
MIAMI FL 33155

Re: K141720
Trade/Device Name: iuStar300 Medical Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 6, 2015
Received: July 15, 2015

Dear Mr. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141720

Device Name: iuStar300 Medical Ultrasound Diagnostic System

Indications for Use:
The iuStar300 Medical Ultrasound Diagnostic System is intended for visualization of internal organs by ultrasound images for medical diagnostic purposes only. It must be operated by qualified and trained Physician or Sonographer. It can be used in following applications: General application, Abdominal, Vascular, OB/GYN, Urology, Breast, Small Parts (breast, thyroid, testes), Musculoskeletal, Superficial Musculoskeletal and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ OR Over-the Counter Use: ____
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ (Specify)	N	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	
	Trans-vaginal	N	N	N		N	N	Note 1	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)	N	N	N		N	N	Note 1	
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1	
	Intravascular								
	Other (Urology)	N	N	N		N	N	Note 1	
	Other (OB/GYN)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ (Per 21 CFR 801.109) OR Over-the Counter Use: ____ (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: L10-5, Linear Array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)	N	N	N		N	N	Note 1	
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)	N	N	N		N	N	Note 1	
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	Note 1	
	Intravascular								
	Other (Specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	Note 1	
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ (Per 21 CFR 801.109) OR Over-the Counter Use: ____ (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: C5-2, Convex

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (OB/GYN)	N	N	N		N	N	Note 1	
	Other (Urology)	N	N	N		N	N	Note 1	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ OR Over-the Counter Use: ____
(Per 21 CFR 801.109) (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: EV9-4, Endo cavity

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	Note 1	
	Trans-vaginal	N	N	N		N	N	Note 1	
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (OB/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ OR Over-the Counter Use: ____
(Per 21 CFR 801.109) (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: V5-2, Volume Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	Note 1	Note 3, 4
	Abdominal	N	N	N		N	N	Note 1	Note 3, 4
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (OB/GYN)	N	N	N		N	N	Note 1	Note 3, 4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ (Per 21 CFR 801.109) OR Over-the Counter Use: ____ (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: MC5-2, Micro Convex

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	Note 1	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (OB/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ (Per 21 CFR 801.109) OR Over-the Counter Use: ____ (Per 21 CFR 807)

Diagnostic Ultrasound Indications For Use

System: iuStar300 Medical Ultrasound Diagnostic System
Transducer: P4-2, Phased array

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1 Only)	**Specific (Tracks 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Combined (Specify)**	**Other* (Specify)**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (OB/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult	N	N	N		N	N	Note 1	
	Cardiac Pediatric	N	N	N		N	N	Note 1	
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix
Note 1: 2D/M, 2D/PW, 2D/C, 2D/PD, 2D/DPD, 2D/PD/PW, 2D/C/PW

Note 2: Tissue Harmonic Imaging Note 3: 3D Note 4: 4D Note 5: Small Organ: breast, thyroid, testes.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use: _✓_ OR Over-the Counter Use: ____
(Per 21 CFR 801.109) (Per 21 CFR 807)

510(k) Summary

510(k) summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based:

The Assigned 510(k) Number is: k141720

1. Submitter Information:

- **Sponsor/510(K) Owner:**
  United Imaging Systems (Beijing) Co., Ltd.
  109 Bldg. 8, No. 8 West Dongbeiwang Rd.
  Haidian District, Beijing 100193
  China
  Phone: 86-10-82894361
  Fax: 86-10-62669095

  Dated: Monday, December 15, 2014

- **Contact Name:**
  Mr. Jun Peng
  P&L SCIENTIFIC, INC.
  6840 SW 45TH LN UNIT 5, MIAMI, FL 33155
  Phone: (305) 609 4701
  Fax: (305) 397 0289
  Email: jpeng@plscientificinc.com

2. Device Name

Trade Name: Medical Ultrasound Diagnostic System, Models iuStar300
Common Name: iuStar300;

3. Classification:

Classification Names	**FR Number**	**Product Code**
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

4. Predicate Devices:

Name	K number	Manufacturer information
ACUSON X300 DIAGNOSTIC ULTRASOUND SYSTEM	K061946	SIEMENS MEDICAL SOLUTIONS USA INC.
S20 DIGITAL COLOR DOPPLER ULTRASOUND SYSTEM	K110510	SONOSCAPE COMPANY LIMITED

5. Description of Device

The iuStar300 Medical Ultrasound Diagnostic System is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms.

iuStar300 Medical Ultrasound Diagnostic System is intended for visualization of internal organs and for medical diagnostic purposes only. It supports 2D, M Mode, CFM and Pulse and Continuous Wave Spectral Doppler, Color Doppler Energy and Directional Color Doppler Energy modes.

6. Intended Use

The iuStar300 Medical Ultrasound Diagnostic System is intended for visualization of internal organs by ultrasound images for medical diagnostic purposes only. It must be operated by qualified and trained Physician or Sonographer. It can be used in following applications: General application, Abdominal, Vascular, OB/GYN, Urology, Breast, Small Parts (breast, thyroid, testes), Musculoskeletal, Superficial Musculoskeletal and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

7. Summary of Comparison in Technological Characteristics to Predicate Device

Name	Predicate device	Predicate device	Subject device
K number	K061946	K110510	k141720
Device Trade Name	ACUSON X300 DIAGNOSTIC ULTRASOUND SYSTEM	S20 DIGITAL COLOR DOPPLER ULTRASOUND SYSTEM	iuStar300 Medical Ultrasound Diagnostic System
Common Name			
Classification Name	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Doppler Imaging System	Ultrasonic Pulsed Doppler Imaging System
Indications for Use	The Siemens Acuson X300 ultrasound imaging system is intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Pans, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications. The system also provides for the	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic(neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.	The iuStar300 Medical Ultrasound Diagnostic System is intended for visualization of internal organs by ultrasound images for medical diagnostic purposes only. It must be operated by qualified and trained Physician or Sonographer. It can be used in following applications: General application, Abdominal, Vascular, OB/GYN, Urology, Breast, Small Parts (breast, thyroid, testes), Musculoskeletal, Superficial Musculoskeletal and Cardiology. Each application includes a set of exams, including the specific measurements, reports, pictograms, annotations and system presets.

	measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.		
Classification			
	Ultrasonic Pulsed Doppler Imaging System 892.1550 IYN Ultrasonic Pulsed Echo Imaging System 892.1560 IYO Diagnostic Ultrasound Transducer 892.1570 ITX	Ultrasonic Pulsed Doppler Imaging System 892.1550 IYN Ultrasonic Pulsed Echo Imaging System 892.1560 IYO Diagnostic Ultrasound Transducer 892.1570 ITX	Ultrasonic Pulsed Doppler Imaging System 892.1550 IYN Ultrasonic Pulsed Echo Imaging System 892.1560 IYO Diagnostic Ultrasound Transducer 892.1570 ITX
Probe Types			
Convex probe	√	√	√
Linear probe	√	√	√
Micro-Convex Probe	√	√	√
Phase array probe	√	√	√
4D Volume probe	√	√	√
Probe frequency			
	2.0MHz -13.0MHz	2.0MHz-12.0MHz	2MHz -14MHz
Modes of Operation			
B-Mode	B-Mode	B-Mode	B Mode
M-Mode	M-Mode	M-Mode	M Mode
Pulsed (PW) Doppler Mode	Pulsed (PW) Doppler mode	Pulsed Doppler	Pulsed (PW) Doppler
Continuous (CW) Doppler Mode	Continuous wave (CW) Doppler mode	Continuous wave (CW) Doppler mode	Continuous wave (CW) Doppler mode
Color Doppler Mode	Color Doppler Mode	Color Doppler Imaging (CDI)	Color Doppler Mode
Amplitude Doppler Mode	Amplitude Doppler Mode	Power Amplitude Doppler Mode	Power Amplitude Doppler Mode
3D Imaging or Harmonic Imaging	3D Imaging or Harmonic Imaging	3D Imaging or Tissue Harmonic Imaging	3D Imaging or Tissue Harmonic Imaging
4D Imaging	4D Imaging	4D Imaging	4D Imaging
Safety & EMC Compliance			
IEC 60601-1	√	√	√

IEC 60601-1-2	√	√	√
IEC 60601-2-37	√	√	√
NEMA UD 2-2004	√	√	√
ISO 10993-1:2009	√	√	√
ISO 10993-5:1999	√	√	√
ISO 10993-10:2002	√	√	√
Acoustic Output Display Standard			
Track 3	√	√	√
Patient Contact Materials			
ISO 10993-1:2009	√	√	√
Functionality			

The subject device is similar to the predicate devices:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

8. Discussion of major difference vs. predicate device

- United Imaging has no Stress Echocardiography function; Sonoscape comes with Stress Echocardiography, Siemens X300 comes with Stress Echocardiography;

Siemens K061946	**SonoScape K110510**	**Subject device iuStar300**	**Conclusion/Discussion**
Tissue harmonic imaging	High Quality Noise Filter	Tissue Harmonic Imaging	The same function.
Doppler Tissue Imaging	Multi-beam Parallel Processing Technology	Digital broadband beam forming	The same function.
Stress Echocardiography	Stress Echocardiography	N/A	iuStar300 has echocardiography function
Tissue harmonic imaging (Improve image contrast and spatial resolution; reduces noise)	µ-Scan	Uniview (Adaptive Speckle Reduction)	Same function used to reduce noise and speckle
SieClear Multi-View Spatial Compounding Option	M-tuning	UniCT (Spatial compound Imaging)	Compound imaging.
Real-time 3D	Real-time 3D(4D)	3D/4D Imaging	Same 3D/4D imaging.

9. Assessment of Non-Clinical Testing:

Non-clinical testing of the iuStar300 Medical Ultrasound Diagnostic System has been performed against requirements for performance, physical attributes, environmental conditions, materials and safety, and to provide objective evidence that the device's intended use is met.

10. Summary Performance Data

- IEC 60601-1 ed3.0 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance 2005-12-15
- EN 60601-1-2, (Third Edition, 2007-07-31), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic
- IEC 60601-2-37:2007 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Edition 2.0, 2007-08-09)
- NEMA UD 2-2004: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- ISO 10993-5:1999: Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- ISO 10993-1:2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- Software validation

11. Conclusion

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is safe and effective as the predicate device.